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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,289

Applicant(s)

SZU ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11/14/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3,6-8,13-15,19-22,24,27,28,30,31,34-36,39 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3,6-8,14-15,19,21-22,24,27-28,30-31,34-36,39,42 is/are rejected.
- 7) ☐ Claim(s) 13,20,34-36 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 4-5, 9-12, 16-18,23, 25-26,29, 32-33, 37-38, and 40-41 have been canceled.

Claims 6, 8, 13-15, 19-22, 24, 27-28, 30, 34-36 and 39 all recite a new combination of claim limitations based upon dependence upon amended independent claims, or being directly amended,

New claim 42 has been added.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

2. Claims 13 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/US 98/14976, filed July 20, 1998. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a



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utility or plant application which **entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application** and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Rejections/Objections Withdrawn

2. Claim 26 is no longer directed to non-statutory subject matter.
3. Claims 8-9 are no longer objected to because of the following informalities: claims 9 and 40 have been canceled.
4. Claims 13-15 are no longer rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as the claims have been amended to recite "pharmaceutically acceptable amount" and now depend from claim 6, rather than claims 10-12.

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5. Claims 16-17, 32, 33 and 41 are no longer rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as the claims have been canceled.

6. Claims 1-3,6,8-9,10-17,19-26,30-34 and 40 rejected under 35 U.S.C. 102(b) as being anticipated by Konadu et al (1998), in view of the effective Declaration under 37 CFR 1.132.

7. Claims 4-5,7,37-38 rejected under 35 U.S.C. 103(a) as obvious over Konadu et al (1998), in view Lees (US Pat. 5,693,326), in light of the effective Declaration under 37 CFR 1.132 removing Konadu et al (1998) as a reference.

8. Claims 34-36,39 rejected under 35 U.S.C. 103(a) as obvious over Taylor et al (1993) in view of Konadu et al (1998), in light of the effective Declaration under 37 CFR 1.132 removing Konadu et al (1998) as a reference.

9. Claims 1-6, 8-11, 13-17, 19=22, 24-25, 26, 34-39, 40 rejected under 35 U.S.C. 102(b) as being anticipated by Konadu et al (symposium and workshop submitted in Applicant's USPTO-1449), in light of the fact that the rejection should have been made under 35 USC 102(a).

10. Claims 10-17,22,24 and 26 rejected under 35 U.S.C. 102(b) as being anticipated by Konadu et al (1994), in light of the amendment of claims 13-16 to no longer depend from claims 10-12(claims 10-12, and 16-17 have been canceled), claims 22, 24 have been amended to recite the species of "human", not the genus of "mammal", and claim 26 has been canceled, as well as a new grounds of rejection set forth below.

11. Claims 10, 13-18 rejected under 35 U.S.C. 102(b) as being anticipated by Moreau et al (US Pat. 6,472,506, effective filing date Jan 21, 1997), in light of the amendment of claim 10, and 16-18 having been canceled), and claims 13-15 having been amended to depend from claim 6, which requires the carrier protein to be a species of Shiga toxin.

12. Claim 22 rejected under 35 U.S.C. 102(b) as being anticipated by Vernozy-Rozand, C (May 1997), in light of the amendment of the claim to recite "human" and shiga toxin B subunit 1 and 2.

13. Claims 22-26 and 40 rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al (1996), in light of the amendment of the claim 22, and 24 having been amended to recite "human" and shiga toxin B subunit 1 and 2; claims 23, 25-26 and 40 have been canceled.

14. Claim 40 rejected under 35 U.S.C. 102(b) as being anticipated by Ashkenazi et al, as claim 40 has been canceled.

15. Claim 40 rejected under 35 U.S.C. 102(b) as being anticipated by Britzan et al, as claim 40 has been canceled.

16. Claim 40 rejected under 35 U.S.C. 102(b) as being anticipated by Burnieet al, as claim 40 has been canceled.

17. Claims 40-41 rejected under 35 U.S.C. 102(b) as being anticipated by Harari et al, as claims 40-41 have been canceled.

18. Claim 22 rejected under 35 U.S.C. 102(b) as being anticipated by Vernozy-Rozand, C (May 1997), in light of the amendment of the claim to recite "human" and shiga toxin B subunit 1 and 2.

19. Claims 22, 24, 26 and 27-28 rejected under 35 U.S.C. 102(b) as being anticipated by Childlow et al (US Pat. 4,141,970), in light of the amendment of the claims to recite "human" and shiga toxin B subunit 1 and 2, and the cancellation of claims 25-26.

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20. Claims 10-18, 20-21, 22,24,26,27-29,32-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Kondau et al (1994) in view of Lees (US Pat. 5,693,326), in view of the species of invention rejected over the combination of these two references have been canceled..

Rejections Maintained

21. Amended Claims 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Chart et al (1989, see Table 1 page 286, and title) , as evidenced by Robbins et al (1992, reference of record, page 350, column 1-2 "Pathogenic Role of Shigella toxins" "Evidence of release of SLTs in vivo is based on rises on rises in titers of specific serum antibodies following convalesces from infection[222]"), wherein Robbins et al shows isolated convalesces serum antibodies to O157 and provides evidence of the inherent presence of serum antibodies to Shiga toxin (E.coli shiga-like toxin), to include the B subunit, in convalescent human serum.

Response to Arguments

22. The rejection of claims 22 and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Chart et al is traversed on the grounds that Chart et al do not teach O157 and Shiga toxin B subunit antibodies.

23. It is the position of the examiner that the composition is not limited to containing "consisting of" only antibodies to O-157 and Shiga toxin B subunit as traversed by Applicant, as the claim recite the term comprising, thus permitting the presence of additional antibodies/immunoglobulin; in view of the Evidence provided in Robbins et al (1992) the human convalescent serum inherently anticipates the instantly claimed invention.

Additionally, claim 22 is directed to two different compositions, one that comprises O157 and Shiga toxin B subunit antibodies and the second composition only comprising antibodies to

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Shiga toxin 2 B subunit. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

New Claim Limitations/New Grounds of Objection/Rejection

Claim Objections

24. Claims 35-36 and 39 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

25. Claims 34 have been amended to depend from claim 1 which only recites a single O-specific polysaccharide, E.coli O157, while being directed to additional O-specific polysaccharides O111, O17 and O26; claim 34 is broader in scope than claim 1 from which it depends and is therefore not further limiting of the base claim from which it depends.

26. Claims 35,36 and 39 depend from claim 34 and therefore recite the additional O-specific polysaccharide species set forth in claim 34, which lack antecedent basis in claim 1, from which claims 35-36, and 39 indirectly depend, and are also not further limiting of claim 1 for the same reasons as claim 34 set forth above.

Claim Rejections - 35 USC § 112

27. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

28. Amended Claim 21 and claim 19 (independent claim from which claim 21 depends) are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

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“inducing in a mammal serum antibodies”, does not reasonably provide enablement for “protect the mammal against infection by E.coli O157”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

29. Claim 21 requires the administered conjugate to not only induce serum antibodies in any mammal but the antibodies must protect that mammal from E.coli O157 infection.

30. The specification fails to teach how to formulate and use the claimed vaccines to “protect against infection by E.coli O157” (instant claim 21) when administered to any mammal, administered by any route, in any dosage amount; critical structural components are not so claimed to enable the method protect against infection.

31. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity to infection or disease induction. The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity when the composition is administered to any mammal, by any route, in any amount for induction of protective immunity against infection, which includes colonization. This demonstration is required for the skilled artisan to be able to use the compositions for their intended purpose of preventing E.coli O157 infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

32. The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the

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identification of the at protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2).

33. Conlan et al (1999) teach the O157 antigen of Escherichia coli O157:H7 to induce systemic antibodies, but the administered glycoconjugate "fails to prevent colonization by the pathogen (see Conlan et al, title)". Conlan et al teach that more than one dosage administration was required to obtain O-specific polysaccharide antibodies (see abstract). Based upon the evidence provided by Conlan et al the instantly claimed invention is not enabled for protection against infection, but only induction of serum antibodies that are bacteriostatic or are partially protective.

34. Additionally, Ludwig et al (2002) teach that antibodies directed to E.coli O157 O-specific polysaccharide fail to induce a long lasting measurable humeral immune response in children with hemolytic uremic syndrome. The mammal to which the glycoconjugate of the instant invention is administered is not limited to any type of patient population, by any specific route of administration, nor required to comprise any specific amount of the conjugate molecule. id antigen preparations.

35. Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

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36. Amended Claims 14-15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

37. Claims 14-15 have been amended to depend from claim 6, instead of claim 10-12; both claims 14 and 15 are directed to identical compositions that comprise 25 ug of E.coli O157 O-specific polysaccharide, and are of the same scope as claim 13, as all three claims, claims 13-15, recite the same compositional components, and the recited intended use of the compositions does not modify what is being claimed in the compositions. Additionally, the scope of claim 13, encompasses the scope of both claims 14 and 15; claims 14 and 15 are duplicative of claim 13.

Claim Rejections - 35 USC § 103

38. Amended claims 6-8, 19,21, 30-31 (31 depends from amended claim 30), 34-36, 39 (depends from amended claims 34-36), new claim 42 and claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konadu et al (1994, reference of record) in view of Robbins et al (1991, reference of record).

Konadu et al (1994) teach the production of an E.coli O157 O-specific polysaccharide protein conjugate (see page 5050, col. 1, line 1), wherein the polysaccharide is conjugated to a bacterial toxin carrier protein (see Table 1), and dialyzed against saline(see Konadu et al, col. 2, page 5049, paragraph 2) or combined with water (page 5049, col. 2, paragraph 1), both saline and water being pharmaceutically acceptable carriers, as well as and administered a composition, with (see page 5049, col. 2, last paragraph) or without (see Table 1) an adjuvant for the induction of serum antibodies but differs from the instantly claimed invention by failing to show the carrier protein to be the B-subunit of Shiga toxin and the mammal to be a human.

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Robbins et al (1991) teaches the formulation of O-specific side chain polysaccharide conjugates , suggests the utilization of the B-subunit of Shiga toxin as a carrier protein (see abstract, page S362), and the administration of the conjugate to a human (young infants, see page S364, col. 1, paragraph 3) in an analogous art for the purpose of inducing Shiga antitoxin antibodies as a means for reducing the severity of dysentery and diarrhea associated with Shigellosis and related diseases (see title).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the conjugate of Konadu et al that comprises detoxified E.coli O-157 O-specific polysaccharide with the B-subunit Shiga toxin protein carrier of Robbins et al in view of the guidance and suggestions provided by Robbins et al because Robbins et al and Konadu et al are both directed to the production of O-specific polysaccharide side chain/carrier protein conjugates for the induction of human serum antibodies, teach E.coli to be a human pathogen that causes dysentery and diarrhea (see Robbins et al, page S363, col. 2, paragraph 4; see Konadu et al, page 5048, col. 1, paragraphs 1-3), that E.coli O157 produces one or two Shiga toxins (Konadu et al, page 5048, col. 1, paragraph 2), that Shiga toxin antibodies may reduce the severity of dysentery and diarrhea associated with Shiga toxin associated disease (see Robbins et al, abstract, page S362 and S364), and the importance of administering a composition to humans (infants, young children) that does not evidence pharmacological properties of LPSs which induce human serum antibodies to O-specific side chain polysaccharides of human pathogens that are able to neutralize the negative effects mediated by lipopolysaccharide virulence (see Robbins et al, abstract, and Konadu et al, abstract, last two sentences).

The person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining an E.coli O-157 O-specific polysaccharide/Shiga toxin B-subunit conjugate that would induce antibodies to both components of the conjugate molecule because Konadu et al teach that means and methods for the attainment of the component parts of the conjugate (see Kondau et al, Material and Methods section; Robbins et al, page S364, col. 1, last paragraph "clinical use"), Konadu et al teach modes of attachment of the two component parts for the conjugate ("polysaccharides with ADH", see page 5049, col. 1-2), and Konadu et al and Robbins et al teach that both O157 and Shiga toxin B-subunit are immunogenic and antiserum directed thereto is expected to provide means for improving the clinical condition of a patient with a O157/Shiga toxin producing pathogen.

Claim Rejections - 35 USC § 102

39. Amended Claims 22, 24, 27 rejected under 35 U.S.C. 102(b) as being anticipated by Bitzan et al (1993, reference made of record in paper number 13) as evidenced by Chart et al (reference of record) that shows humans produce antibodies to both E.coli O-specific polysaccharide and shiga toxin.

Bitzan et al disclose compositions of human immunoglobulin (see page 142, Table 3) with neutralizing activity directed against Shiga toxin (see VT1 and VT2, page 143, col. 2, second paragraph, middle of paragraph, which are shiga like toxin 1 and Shiga toxin 2), and would therefore inherently comprise polyclonal antibodies directed against Shiga toxin B subunit (see Table 2, top of col. 2, page 142). Inherently the reference anticipates the instantly claimed human immunoglobulin compositions that comprise anti Shiga B subunit antibodies and antibodies directed against E.coli O-157:H7 antigen (see page 141, col. 2, E.coli O157:H7

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produce verotoxins; aka: shiga toxins) as evidenced by Chart et al that show humans produce immunoglobulins to both O-157 and Shiga toxin, which comprises the B-subunit.

Bitzan et al also disclose that human immunoglobulins have been used in a method of passively immunizing a human (see page 144, col. 2, line 1), the method comprising the step of administering human immunoglobulin (0.4 g/kg, page 144, col. 2, first paragraph near bottom) in a sufficient amount (see Bitzan et al, see abstract, references of Bibliography 45 and 46; page 144, col. 1, last paragraph). The reference inherently anticipates the instantly claimed invention.

40. Amended Claims 22, 24, 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashkenazi et al (1988, reference made of record in paper number 13) as evidenced by Chart et al (reference of record) that shows humans produce antibodies to both E.coli O-specific polysaccharide and shiga toxin..

Ashkenazi et al disclose compositions of human immunoglobulin (see page 1009, col. 2, paragraph 2) with neutralizing activity directed against Shiga toxin (see Figure 2, page 1011), and would therefore inherently comprise polyclonal antibodies directed against Shiga toxin B subunit (see page 1009, col. 2 and page 1010, col. 1, paragraph 2, and column 2, paragraph 3). Inherently the reference anticipates the instantly claimed human immunoglobulin compositions that comprise anti Shiga B subunit antibodies and antibodies directed against E.coli O-157:H7 antigen (see page 1009, col.1, paragraph 1) as evidenced by Chart et al that show humans produce immunoglobulins to both O-157 and Shiga toxin, which comprises the B-subunit.

Ashkenazi et al also disclose that human immunoglobulins have been used in a method of passively immunizing a human, the method comprising the step of administering human

immunoglobulin in a sufficient amount (see Ashkenazi et al, see abstract "IVIG therapy has been reported to be beneficial in a few children with HUS"; page 1009, col. 1, paragraph 3). The dosage was prepared in the concentration usually used clinically (see page 1009, col. 2, paragraph 2; 5gm/dl). The reference inherently anticipates the instantly claimed invention.

Conclusion

41. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

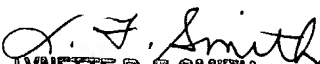
42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
May12, 2004


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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600